REMARKS

The Office Action of May 10, 2004, has been received and reviewed. Claims 17-27, 29-31, 33-41, and 49-53 are currently pending in the application and all pending claims stand rejected. In view of the remarks presented herein, reconsideration is requested.

Information Disclosure Statement(s)

Applicants note the filing of Information Disclosure Statements herein on July 28, 2000, and on or about November 1, 2000, and note that no copies of the PTO-1449s were returned with the outstanding Office Action. Applicants respectfully request that the information cited on the PTO-1449s be made of record herein. Should the Information Disclosure Statements have failed to reach the Office, applicants representatives will have the references forwarded to the Office.

35 U.S.C. § 112 Claim Rejections

Claims 33-35 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

Specifically, the Examiner stated that explanation was required since "suspensions are not single-phase formulations." (Office Action, page 2). Claim 33 is directed to a "method for preparing a formulation comprising at least one beneficial agent and a non-aqueous, single-phase biocompatible vehicle." Claim 33 further recites "preparing a substantially uniform suspension of the at least one beneficial agent by combining the vehicle and the at least one beneficial agent." Thus, the at least one beneficial agent is combined with the non-aqueous, single-phase biocompatible vehicle, wherein the at least one beneficial agent is **suspended** in the vehicle to form the formulation (i.e., the single-phase formulation is used to form a suspension).

Accordingly, since one of ordinary skill in the art would understand that the method of claim 33 includes using the non-aqueous, single-phase biocompatible vehicle to **suspend** the at least one beneficial agent to form the formulation, claim 33 is definite.

Claims 34 and 35 are definite as depending from definite claim 33.

Reconsideration and withdrawal of the indefiniteness rejections of claims 33-35 are requested.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 4,376,118 to Daher et al.

Claims 17-19, 24-31, 36, 52, and 53 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Daher et al. (U.S. Patent No. 4,376,118). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (*Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The identical invention must be shown in as complete detail as is contained in the claim. (*Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Daher et al. cannot anticipate any of independent claims 17, 18 or 36 since Daher et al. does not expressly or inherently disclose each and every of any of claims 17, 18 or 36.

Claim 17 is directed to, *inter alia*, a formulation comprising at least one beneficial agent and a non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent is lauryl acetate. Daher et al. does not identically disclose a "beneficial agent" as recited in claim 17 since the as-filed specification provides a clear definition of the "beneficial agent." (*See*, Specification, as-filed page 10, line 21) Specifically, the specification recites that

> [t]he term "beneficial agent" means peptides, proteins, nucleotides, hormones, viruses, antibodies, etc. that comprise polymers of amino acid or nucleic acid residues. These beneficial agents are generally degradable in water and generally stable as a dry powder at elevated temperatures. Synthetically produced, naturally derived or recombinantly produced moieties are included in this term. The term also includes lipoproteins and post translationally modified forms, e.g., glycosylated proteins. Analogs, derivatives, agonists, antagonists and pharmaceutically acceptable salts of any of these are included in this term. The term also includes proteins and/or protein substances which have D-amino acids, modified, derivatized or non-naturally occurring amino acids in the D- or L-configuration and/or peptomimetic units as part of their structure. The term protein will be used in the present invention. The term also means that the beneficial agent is present in the solid state, e.g., powder or crystalline.

(*I.d*). M.P.E.P. § 2111.01 indicates that when terms of a claim are defined in the specification, the term must be interpreted in light of the definition. Thus, when claim 17 is read in light of the definition of a "beneficial agent" as defined in the as-filed specification, Daher et al. does not identically disclose the beneficial agent of claim 17, but rather Daher et al. is limited to the use of a "tetracycline antibiotic salt." (*See*, Daher et al., Col. 1, lines 34-41 and claim 1).

Claim 17 further cannot be anticipated since Daher et al. does not identically disclose the solvent of claim 17. Claim 17 recites that "the solvent is lauryl lactate." As stated in Daher et al. "[t]he nonaqueous solvent can be ethanol, methanol, isopropanol, butanol, N-methyl-2-pyrrolidone or acetone. Ethanol is the preferred solvent." (Daher et al. at Col. 1, lines 51-53). Since Daher et al. does not identically disclose lauryl lactate as the solvent as recited in claim 17, claim 17 cannot be anticipated.

Claims 19, 24-27 and 29-31 are novel, at the very least, as depending from novel independent claim 17.

Independent claim 18 also cannot be anticipated since Daher et al. does not identically disclose each and every element of claim 18. Claim 18 is directed to a non-aqueous formulation comprising at least one beneficial agent suspended in a vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent is lauryl lactate. As previously established herein, Daher et al. does not identically disclose the beneficial agent as described in the as-filed specification or lauryl lactate as a solvent as recited in claim 18. (*See*, Specification, *supra*; *see also* Daher et al., *supra*). As Daher et al. does not identically disclose each and every element of claim 18, it cannot be anticipated.

Daher et al. also cannot anticipate independent claim 36 since it does not identically disclose each and every element of claim 36. Daher et al. does not identically disclose a method of treating a subject comprising administering a therapeutically effective amount of a formulation comprising at least one beneficial agent and a non-aqueous, single-phase biocompatible vehicle comprising a solvent, a surfactant, and a polymer, wherein the solvent is lauryl lactate. As previously established herein, Daher et al. does not identically disclose a formulation having lauryl lactate as a solvent or the beneficial agent as described in the as-filed specification as required to anticipate independent claim 36. (*See*, Specification, *supra*; *see also* Daher et al., *supra*).

Claims 52 and 53 are not anticipated, at the very least, as depending from novel independent claim 36.

Reconsideration and withdrawal of the anticipation rejections of claims 17-19, 24-31, 36, 52, and 53 are requested.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al.

Claims 20 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (*emphasis added*)).

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." (*See, In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Thus, claims 20 and 21 are nonobvious, at the very least, as depending from novel independent claim 17. Further, Daher et al. does not, alone or modified, teach or suggest each and every element of claim 20 or 21 as required to establish a *prima facie* case of obviousness. For instance, as claims 20 and 21 depend from claim 17 and Daher et al. does not teach or suggest each and every element of the formulation of claim 17 (*i.e.*, "a beneficial agent" as defined in the specification; and lauryl lactate as a solvent), a modification of Daher et al. also does not teach or suggest each and every element of claims 20 and 21.

Reconsideration and withdrawal of the obviousness rejections of claims 20 and 21 are requested.

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al.

Claims 40, 41, and 49 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 40 and 41 are nonobvious, at the very least, as depending from nonobvious independent claim 36. (*See, Id.*). Claim 49 is nonobvious, at the very least, as depending from nonobvious independent claim 17. (*See, Id.*). Further, Daher et al. does not, alone or modified, teach or suggest each and every element of claims 40, 41 or 49 as required to establish a *prima facie* case of obviousness. For instance, as claims 40 and 41 depend from claim 36 and claim 49 depends from claim 17, and Daher et al. does not teach or suggest each and every element of the method of claim 36 or each and every element of the formulation of claim 17 (*i.e.*, "a beneficial agent", or use thereof, as defined in the specification; and lauryl lactate, or use thereof, as a solvent), a modification of Daher et al. also does not teach or suggest each and every element of claims 40, 41 or 49.

Reconsideration and withdrawal of the obviousness rejections of claims 40, 41 and 49 are requested.

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. in View of U.S. Patent No. 5,290,271 to Jernberg

Claim 39 stands rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) in view of Jernberg (U.S. Patent No. 5,290,271). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claim 39 is nonobvious, at the very least, as depending from nonobvious claim 36. (*See, Id.*). Further, Daher et al. does not alone or in combination with Jernberg teach or suggest each and every element of claim 39 as required to establish a *prima facie* case of obviousness. For instance, as claim 39 depends from claim 36 and Daher et al. does not teach or suggest each and every element of the method of claim 36 (*i.e.*, use of "a beneficial agent" as defined in the specification and use of lauryl lactate as a solvent), a resultant combination of Jernberg with Daher et al. also does not teach or suggest each and every element of claim 39.

Reconsideration and withdrawal of the obviousness rejection of claim 39 are requested.

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. in View of British Patent No. GB 1,049,104 to Societa Prodotti Antibiot

Claims 37 and 38 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) in view of Societa Prodotti Antibiot (British Patent No. GB 1,049,104). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 37 and 38 are nonobvious, at the very least, as depending from nonobvious independent claim 36. (*See, Id.*). Further, Daher et al. does not alone or in combination with GB 1,049,104 teach or suggest each and every element of claims 37 and 38 as required to establish a *prima facie* case of obviousness. For instance, as claims 37 and 38 depend from claim 36 and Daher et al. does not teach or suggest the each and every element of the method of claim 36 (*i.e.*, use of "a beneficial agent" as defined in the specification and use of lauryl lactate as a solvent), a resultant combination of GB 1,049,104 with Daher et al. also does not teach or suggest each and every element of claims 37 and 38.

Reconsideration and withdrawal of the obviousness rejections of claims 37 and 38 are requested.

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. in View of U.S. Patent No. 3,632,768 to Bergy et al.

Claims 50 and 51 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) in view of Bergy et al. (U.S. Patent No. 3,632,768). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 50 and 51 are nonobvious, at the very least, as depending from nonobvious independent claims 17. (*See, Id.*). Further, Daher et al. does not alone or in combination with Bergy et al. teach or suggest each and every element of claims 50 and 51 as required to establish a *prima facie* case of obviousness. For instance, as claims 50 and 51 depend from claim 17 and Daher et al. does not teach or suggest each and every element of the formulation of claim 17 (*i.e.*, "a beneficial agent" as defined in the specification; and lauryl lactate as a solvent), a resultant

combination of Bergy et al. with Daher et al. also does not teach or suggest each and every element of claims 50 and 51.

Reconsideration and withdrawal of the obviousness rejections of claims 50 and 51 are requested.

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. in View of U.S. Patent No. 5,284,655 to Bogdansky et al.

Claims 22 and 23 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) in view of Bogdansky et al. (U.S. Patent No. 5,284,655). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 22 and 23 are nonobvious, at the very least, as depending from nonobvious independent claim 22. (*See, Id.*).

The 35 U.S.C. § 103(a) obviousness rejections of claims 22 and 23 are improper because a *prima facie* case of obviousness cannot be established since Daher et al. does not alone, or in combination with Bogdansky, teach or suggest each and every element of claim 22 or 23 as required for obviousness. For instance, as previously established herein, Daher et al. does not disclose lauryl lactate as a solvent and Bogdansky does not remedy the deficiency of Daher et al. in this regard.

With further regard to dependent claims 22 and 23, no suggestion or motivation exists to combine Daher et al. with Bogdansky. The Office Action indicated that "protein and tetracycline are equivalent as active agents in Bogdansky. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the tetracycline formulation of Daher. One would have been motivated to substitute protein for tetracycline with the expectation that the protein containing formulation will be flowable and suitable for implantation." (Office Action at page 6).

However, Bogdansky does not indicate that protein and tetracycline are equivalent as active agents as asserted in the Office Action. Bogdansky merely indicates that "medically/surgically useful substances which can be readily incorporated in the osteogenic composition include [a laundry list of compounds]..." (Bogdansky, Col. 5, lines 47-49). "The mere fact that references can be combined or modified does not render the resultant combination

obvious unless the prior art also suggests the desirability of the combination." (M.P.E.P. § 2143.01 *citing In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (emphasis in original)). Since Daher et al. does not suggest or motivate the use of a peptide and Bogdansky does not suggest or motivate the use of a stable nonaqueous solution including a nonaqueous diluent, nonaqueous solvent and nonaqueous nonionic solubilizer and is limited to a flowable osteogenic composition, no suggestion or motivation exists to combine Daher et al. with Bogdansky. Thus, a *prima facie* case of obviousness cannot be established with regard to claims 22 and 23.

Reconsideration and withdrawal of the obviousness rejections of claims 22 and 23 are requested.

CONCLUSION

Claims 17-27, 29-31, 33-41, and 49-53 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, it is respectfully invited to contact applicants' undersigned attorney.

Respectfully submitted,

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